

CORE CENTERS FOR MUSCULOSKELETAL DISORDERS

NIH Guide, Volume 26, Number 39, December 5, 1997

RFA: AR-98-004

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: May 15, 1998

Application Receipt Date: July 15, 1998

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) in musculoskeletal disorders. The Core Centers for Musculoskeletal Disorders (CCMDs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in musculoskeletal disorders and to ensure greater productivity than from each of the separate projects.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Core Center for Musculoskeletal Disorders, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. An established clinical and basic

research program in musculoskeletal disorders must be present. Applications from racial/ethnic minority individuals and women and persons with disabilities are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH Core Center Grant (P30). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Investigators are to request five years of support. The anticipated award date is April 1, 1999.

FUNDS AVAILABLE

The direct costs requested cannot exceed \$400,000 each year. The NIAMS intends to fund up to two P30 applications responding to this RFA in FY 1999, subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are \$1.2 million.

RESEARCH OBJECTIVES

Research in musculoskeletal disorders is at a stage where a number of areas are making broad advances that can be effectively fostered by research core centers. Examples of these areas include, but are not limited to:

- o Regulation of skeletal growth and remodeling by systemic and local factors; diagnostic markers of skeletal remodeling; genetic basis of skeletal morphogenesis, growth, and disease.
- o Mechanisms of bone repair and regeneration, including fracture healing; development of techniques for growth plate repair, reconstitution of large defects, and limb lengthening, including use of autografts and allografts, and distraction osteogenesis.
- o Mechanisms of cartilage repair and regeneration, including chondroprogenitor cell biology, genetics, and biomechanical signalling; development of techniques for chondroprotection and repair of the articular surface, including gene therapy approaches.

The choice of research area upon which the CCMD would focus is made by the principal and collaborating currently funded investigators.

The CCMDs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities.
2. Up to \$100,000 yearly in direct costs for pilot and feasibility studies.
3. Program enrichment activities.
4. Administrative Core

A CCMD should be an identifiable organizational unit within a university-affiliated medical center. An Administrative Core should be proposed to coordinate the Center and administer the program enrichment activities. Two or more research cores must be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics).

A pilot and feasibility study program provides modest research support (\$20,000 - \$50,000 yearly) for a limited time (1 to 3 years) to enable eligible investigators to explore the feasibility of a musculoskeletal disorders-related concept and amass sufficient data to pursue it through other funding mechanisms. An investigator is eligible only once every 5 years. Eligible investigators include

1. an established investigator in musculoskeletal disorders or related areas with a proposal for testing the feasibility of a new or innovative idea that is musculoskeletal disorders-related but represents a clear and distinct departure from the investigator's ongoing research interest;
2. an established, supported investigator with no previous work in musculoskeletal disorders or related areas who is willing to test the applicability of his/her expertise on a musculoskeletal disorders-related problem; and
3. a new investigator who has not been a principal investigator in a past or current NIH research project grant (R01, R29, P01) or a current R55 grant. New investigators should be clearly

independent and have a faculty appointment higher than that of postdoctoral fellow or research associate.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the CCMD staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one-day meeting in Bethesda, MD with NIAMS staff.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 15, 1998, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent

applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the selection of reviewers. The letter of intent is to be sent to Dr. Julia B. Freeman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Special guidelines have been developed for Core Centers supported by NIAMS. These guidelines should be used in assembling the application. See INQUIRIES for obtaining a copy of these guidelines.

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: ASKNIH@od.nih.gov.

The RFA label available in the PHS 398 (rev. 5/95) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, "Core Center for Musculoskeletal Disorders", and number, "AR-98-004" must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW (formerly Division of Research Grants)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send two additional copies of the application to:

Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS.25U - MSC 6500
Bethesda, MD 20892-6500

Bethesda, MD 20814 (for express/courier service)

Applications must be received by July 15, 1998. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Applications for Core Center grants will first be screened for completeness by the Center for Scientific Review (formerly DRG) and for responsiveness by NIAMS staff. Applications that are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine their scientific merit relative to the other applications received in response to this RFA; the NIH will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator and the official signing for the applicant organization.

Those applications judged to be competitive will be further evaluated for scientific merit by a group of expert consultants convened by the Review Branch of the NIAMS. Each proposal should be complete in itself. Revisions will not be accepted after the receipt date. Site visits are not anticipated. It is strongly recommended that, if appropriate, Institutional Review Board (IRB) and Institutional Animal Care and Use committee (IACUC) approval be secured before the application is submitted. Otherwise, it is the applicant's responsibility to ensure these certifications are sent to the NIAMS Review Branch within 60 days of the receipt date.

Applications failing to comply with this requirement will be returned without review. A second level of review will be performed by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Review criteria

Applicants should clearly demonstrate the ways in which the CCMD will build the local research program, will support on-going projects and will attract both senior and new investigators to musculoskeletal disorders research. Review criteria which will be used by the initial review group (IRG) in the evaluation of the Core Center applications follow:

1. Evaluation of Cores

A research core is evaluated on the facilities and or services provided.

Important factors include:

Significance: Will the core have utility to the Core Center research base (minimum: two independently funded investigators)?

Approach: Are the quality of services high? Are there procedures for quality control? Is the core cost effective? How is cost reimbursement proposed?

Innovation: Will the core likely promote interdisciplinary research? Are unique services offered?

Investigator: Are the personnel appropriate?

Environment: Are the facilities and equipment adequate? Is there institutional commitment to the core?

2. Evaluation of Pilot and Feasibility Studies (P&Fs)

For individual P&Fs:

Significance: Will the proposed work likely yield meaningful preliminary data leading to a research proposal?

Approach: Are the experimental approaches adequate?

Innovation: Is the research topic one that promotes innovative new research related to the core center?

Investigator: Does the investigator meet one of the criteria for P&F investigators? (If not, the project should not be considered further.)

Environment: Is the project appropriate to the research base of the core center?
Does one or more of the cores offer needed materials/assistance?

3. Evaluation of the Administrative Core

The Administrative Core is evaluated on the leadership provided. Important factors include:

Significance: Does the proposed Core Center document coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring?

Approach: Is the management proposed appropriate for 1) fiscal administration, procurement, property and personnel management, planning, budgeting, etc.; 2) reviewing the use of, and administering funds for, the pilot and feasibility program? Are the Core Center budgets appropriate for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Core Center program?

Innovation: Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators and for an enrichment program that provides outside review and input?

Investigators: Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the Core Center Director and Associate Director for the effective management of the Core Center program?

Environment: Have institutional lines of authority and sanction been documented for the Core Center?

4. Overall Core Center Evaluation

An overall priority score will be assigned to the application. This score will reflect not only the quality of the cores, administration, and pilot and feasibility studies, but also the quality of the research base and how the proposed Core Center will enhance the research base.

The following elements will be evaluated:

a. The scientific excellence of the Core Center's research base as well as the relevance and interrelation of these separately funded research projects to the central themes of the Core Center and the likelihood for meaningful collaboration among Core Center investigators. Existence of a base of established independently supported biomedical research of high quality is a prerequisite for establishment of a Core Center.

b. The application must convey how the proposed Core Center will enhance significantly the cited research base established at the host institution. This includes the qualifications, experience, and

commitment of the Core Center investigators and their willingness to interact with each other. This also includes efficient and effective use and/or planned use of enrichment funds including the contribution of these activities in enhancing the realization of the Core Center concept.

- c. The appropriateness, quality and relevance of the proposed cores, and the modes of operation, facilities, and potential for contribution to ongoing research.
- d. The proposed management of the pilot and feasibility program and the scientific merit of the pilot and feasibility projects for which funds are requested from the Core Center grant. The effectiveness of the proposed program will serve as a basis for recommendations concerning the level at which pilot and feasibility studies will be supported throughout the project period.
- e. The overall environment for a Core Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Core Center, and the institution's partnership with the Core Center, and the institutional commitment to individuals responsible for conducting essential Core Center functions. This also includes the academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Since the NIAMS is interested in funding only the best research, individual components of lesser quality may not be funded, even if approved, under the "umbrella" of the Core Center grant mechanism. It is primarily for this reason that each component will be assigned a separate merit rating, taking into consideration only its merit as an individual pilot and feasibility study or core.

AWARD CRITERIA

The anticipated date of award is April 1999. The primary factors determining the award will be the priority score and the availability of funds. Since the NIAMS is interested in funding only the best research, individual pilot and feasibility projects or cores of lesser quality may not be funded, even if approved, under the "umbrella" of the CCMD mechanism.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Inquiries regarding programmatic issues and letters of intent may be directed to:

Dr. Julia B. Freeman
Centers Program, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases Natcher
Building, Room 5AS.19F - MSC 6500
Bethesda, MD 20892-6500
Bethesda, MD 20814 (for express/courier service)
Telephone: (301) 594-5052
FAX: (301) 480-4543
Email: Julia_B_Freeman@nih.gov

Copies of the guidelines for the NIAMS CORE CENTER program may be obtained from:

NIAMS Clearinghouse
1 AMS Circle
Bethesda, MD 20892-3675
Telephone: (301) 495-4484
FAX: (301) 587-4352

Guidelines are also available on the internet:

<http://www.nih.gov/niams/grants/ep7.htm>

Direct inquiries regarding fiscal matters to:

Sally A. Nichols
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases Natcher
Building Room 5AS.49F - MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nicholss@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the

Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)